MAR 2 2 2012

510(k) Summary - K113657

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

Manfred Stever
Philips Medizin Systeme Boeblingen GmbH
Hewlett-Packard-Str. 2
D-71034 Boeblingen, Germany
Tel: ++49 7031 463-2186 Fax: ++49 7031 463-2442
e-mail: manfred.stever@philips.com

This summary was prepared on March 14, 2012.

2. The names of the devices are the Philips MP2, X2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX600, MX700 and MX800 IntelliVue patient monitors
Classification names are as follows:

Device Panel	Classification	ProCode	Description
Cardiovascular Devices	§870.1025, II	DSI	Detector and alarm, arrhythmia
	§870.1025, II	MLD	Monitor, ST Segment with Alarm
	§870.1025, II	MHX	Arrhythmia detector and alarm (including ST-segment measurement and alarm)
	§870.1100, II	DSJ	Alarm, Blood Pressure
	§870.1110, II	DSK	Computer, Blood Pressure
	§870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	§870.1435, II	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
	§870.1915, II	KRB	Probe, Thermodilution
	§870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	§870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	§870.2340, II	DPS	Electrocardiograph
	§870.2340, II	MLC	Monitor, ST Segment
	§870.2350, II	DRW	Electrocardiograph, Lead Switching Adapter
	§870.2370, II	KRC	Tester, Electrode, Surface, Electrocardiograph
	§870.2600, I	DRJ	System, Signal Isolation
	§870.2700, II	DQA	Oximeter
	§870.2770, II	DSB	Plethysmograph, Impedance
	§870.2800, II	DSH	Recorder, Magnetic tape, Medical
	§870.2810, I	DSF	Recorder, Paper Chart
	§870.2850, II	DRS	Extravascular Blood Pressure Transducer

Device Panel	Classification	ProCode	Description
	§870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
	-	MSX	System, Network and Communication, Physiological Monitors
	§870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency
Anesthesiology Devices	§868.1400, II	CCK	Analyzer, Gas, Carbon Dioxide, Gaseous-Phase
	§868.1500, II	CBQ	Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHO	Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHP	Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHQ	Analyzer, Gas, Isoflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1620, II	CBS	Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Concentration)
	§868.1700, II	CBR	Analyzer, Gas, Nitrous Oxide, Gaseous-Phase (Anesthetic Concentration)
	§868.1720, II	CCL	Analyzer, Gas, Oxygen, Gaseous-Phase
	§868.1880, II	BZC	Data calculator Pulmonary-function
	§868.2375, II	BZQ	Monitor, Breathing Frequency
	§868.2480, II	LKD	Monitor, Carbon Dioxide, Cutaneous
	§868.2500, II	KLK	Monitor, Oxygen, Cutaneous, for Infant not under Gas Anesthesia
General Hospital and Personal Use Devices	§880.2910, II	FLL	Thermometer, Electronic, Clinical
Neurological Devices	§882.1400, II	GWR	Electroencephalograph
	§882.1420, I	GWS	Analyzer, Spectrum, Electroencephalogram Signal

3. The modified devices are substantially equivalent to previously cleared Philips IntelliVue patient monitors marketed pursuant to K110622, K102562, K101449, K100939, K093268, K091927, K083517, K082633, K081793, K072070, K071426, K063725, K063315, K062283, K062392, K061610, K061052, K060541, K060221, K053522, K052801, K051106, K050762, K050141, K042845, K041235, K040304, K033513, K033444, K032858, K031481, K030038, K023871, and K021778

4. The Philips IntelliVue Patient Monitor family comprises the multi-parameter patient monitor models: MP2, X2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX600, MX700 and MX800 IntelliVue Patient Monitors that consist of display units including built-in or separate flat panel displays and central processing units (CPU) and physiological measurement modules. All monitors share the same system architecture and exactly the same software is executed on each monitor.
   The IntelliVue Patient Monitors measure multiple physiological parameters such as surface ECG, invasive and non-invasive pressure, etc., generate alarms, record physiological signals, store derived data, and communicate derived data and alarms to central stations via the IntelliVue Clinical Network.
   The subject modification is enhancement of ProtocolWatch SCC Sepsis protocol by an introduction of configurable thresholds, modification of sepsis criteria and free text fields within the Sepsis Resuscitation Bundle and Sepsis Management Bundle phase of SSC Sepsis protocol.

   Additionally the software revision J.03 is made available for the entire IntelliVue Patient Monitors family.

5. The modified devices have the same intended use as the legally marketed predicate devices.

   <u>MP2 IntelliVue Patient monitor:</u>

   The monitor is indicated for use by healthcare professionals whenever there is a need for monitoring the physiological parameters of patients.
   The monitor is intended to be used for monitoring and recording of, and to generate alarms, for, multiple physiological parameters of adults, pediatrics, and neonates. The monitor is intended for use by trained healthcare professionals in a hospital environment.
   The monitor is also intended for use during patient transport inside and outside of the hospital environment.
   The monitor is only for use on one patient at a time. It is not intended for home use. Not a therapeutic device. The monitor is for prescription use only.
   The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).
   ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.

MP5, MP5T and MP5SC IntelliVue Patient Monitor:

The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.
The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates.
The monitors are intended for use by trained healthcare professionals in a hospital environment.
The MP5, MP5SC and MP5T monitors are also intended for use during patient transport inside the hospital environment; only the MP5 monitor is for use during patient transport outside of the hospital environment. The MP5, MP5SC and MP5T when used with the TRx4841A/TRx4851A IntelliVue
Telemetry System Transceiver or with the IntelliVue Cableless Measurement Devices, are intended for use in a hospital environment and during patient transport inside the hospital environment.
The monitors are only for use on one patient at a time. They are not intended for home use. Not therapeutic devices. The monitors are for prescription use only.
The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.
The Predictive Temperature unit is intended for use with adult and pediatric patients in a hospital environment.
The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.
The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.

MP20 - MP90 IntelliVue Patient Monitor:

The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.
The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates.
The monitors are intended for use by trained healthcare professionals in a hospital environment.
The MP20/MP30/MP40/MP50 monitors are additionally intended for use in transport situations within hospital environments.
The monitors are only for use on one patient at a time. They are not intended for home use. Not therapeutic devices. The monitors are for prescription use only.

The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.
The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.
The transcutaneous gas measurement (tcGas) is restricted to neonatal patients only.
BIS is intended for use under the direct supervision of a licensed health care practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The BIS may be used as an aid in monitoring the effects of certain anesthetic agents.
Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.
The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.

MX600, MX700 and MX800 IntelliVue Patient Monitor:

The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.
The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates.
The monitors are intended for use by trained healthcare professionals in a hospital environment.
The monitors are only for use on one patient at a time. They are not intended for home use. Not therapeutic devices. The monitors are for prescription use only.
The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.
The transcutaneous gas measurement (tcGas) is restricted to neonatal patients only.
BIS is intended for use under the direct supervision of a licensed health care practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The BIS may be used as an aid in monitoring the effects of certain anesthetic agents.

Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.
The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.
The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.

X2 Multi-Measurement Module:

The monitor is indicated for use by healthcare professionals whenever there is a need for monitoring the physiological parameters of patients.
The monitor is intended to be used for monitoring and recording of, and to generate alarms, for, multiple physiological parameters of adults, pediatrics, and neonates. The monitor is intended for use by trained healthcare professionals in a hospital environment.
The monitor is also intended for use during patient transport inside and outside of the hospital environment.
The monitor is only for use on one patient at a time. It is not intended for home use. Not a therapeutic device. The monitor is for prescription use only.
The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.

6. The modified devices have the same technological characteristics as the legally marketed predicate device.

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified devices with respect to the predicate. Testing involved system level and as well as testing from the hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence. The results demonstrate that the Philips IntelliVue patient monitors meet all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

MAR 2 2 2012

Philips Medizin Systeme Böblingen GmbH
c/o Mr. Manfred Stever
Sr. Regulatory Affairs Engineer
Hewlett-Packard-Str. 2
Boeblingen
Germany D-71034

Re: K113657
Trade/Device Name: IntelliVue Patient Monitors Model MP2, X2, MP5, MP5T, MP5SC, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90, MX600, MX700 and MX800
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (two)
Product Code: MHX, DSI, MLD, DSJ, DSK, DXN, DXG, KRB, DRQ, DRT, DPS, MLC, DRW, KRC, DRJ, DQA, DSB, DSH, DSF, DRS, DSA, MSX, DRG, CCK, CBQ, NHO, NHP, NHQ, CBS, CBR, CCL, BZC, BZQ, LDK, KLK, FLL, GWR, GWS.
Dated: February 21, 2012
Received: February 23, 2012

Dear Mr. Stever:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.1 Indications Statement

Indications for Use MP2

510(k) Number (if known): K113657

Device Name: Philips MP2 IntelliVue patient monitor, software revision J.03.

MP2 IntelliVue Patient monitor:

The monitor is indicated for use by healthcare professionals whenever there is a need for monitoring the physiological parameters of patients.
The monitor is intended to be used for monitoring and recording of, and to generate alarms, for, multiple physiological parameters of adults, pediatrics, and neonates. The monitor is intended for use by trained healthcare professionals in a hospital environment.
The monitor is also intended for use during patient transport inside and outside of the hospital environment.
The monitor is only for use on one patient at a time. It is not intended for home use. Not a therapeutic device. The monitor is for prescription use only.
The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.

Prescription Use (Part 21 CFR 801 Subpart D)	___Yes__	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	__No___

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113657

Indications for Use MP5, MP5T and MP5SC

510(k) Number (if known):_____

Device Name: Philips MP5, MP5T and MP5SC IntelliVue patient monitors, software revision J.03.

MP5, MP5T and MP5SC IntelliVue Patient Monitor:

The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.
The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitors are intended for use by trained healthcare professionals in a hospital environment.
The MP5, MP5SC and MP5T monitors are also intended for use during patient transport inside the hospital environment; only the MP5 monitor is for use during patient transport outside of the hospital environment. The MP5, MP5SC and MP5T when used with the TRx4841A/TRx4851A IntelliVue Telemetry System Transceiver or with the IntelliVue Cableless Measurement Devices, are intended for use in a hospital environment and during patient transport inside the hospital environment.
The monitors are only for use on one patient at a time. They are not intended for home use. Not therapeutic devices. The monitors are for prescription use only.
The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.
The Predictive Temperature unit is intended for use with adult and pediatric patients in a hospital environment.
The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.
The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.

Prescription Use (Part 21 CFR 801 Subpart D)	___Yes__	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	__No___

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113657

Indications for Use MP20-90

510(k) Number (if known):_____

Device Name: Philips MP20, MP30, MP40, MP50, MP60, MP70, MP80 and MP90 IntelliVue patient monitors, software revision J.03.

MP20 - MP90 IntelliVue Patient Monitor:

The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.
The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitors are intended for use by trained healthcare professionals in a hospital environment.
The MP20/MP30/MP40/MP50 monitors are additionally intended for use in transport situations within hospital environments.
The monitors are only for use on one patient at a time. They are not intended for home use. Not therapeutic devices. The monitors are for prescription use only.
The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.
The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.
The transcutaneous gas measurement (tcGas) is restricted to neonatal patients only.
BIS is intended for use under the direct supervision of a licensed health care practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The BIS may be used as an aid in monitoring the effects of certain anesthetic agents.
Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.
The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.

Prescription Use (Part 21 CFR 801 Subpart D)	___Yes__	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	__No___

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113657

Indications for Use MX600-MX800

510(k) Number (if known):_____

Device Name: Philips MX600, MX700 and MX800 IntelliVue patient monitors, software revision J.03.

MX600, MX700 and MX800 IntelliVue Patient Monitor:

The monitors are indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.
The monitors are intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitors are intended for use by trained healthcare professionals in a hospital environment.
The monitors are only for use on one patient at a time. They are not intended for home use. Not therapeutic devices. The monitors are for prescription use only.
The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.
The transcutaneous gas measurement (tcGas) is restricted to neonatal patients only.
BIS is intended for use under the direct supervision of a licensed health care practitioner or by personnel trained in its proper use. It is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals. The BIS may be used as an aid in monitoring the effects of certain anesthetic agents.
Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.
The SSC Sepsis Protocol, in the ProtocolWatch clinical decision support tool, is intended for use with adult patients only.
The derived measurement Pulse Pressure Variation (PPV) is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from cardiac arrhythmia. The PPV measurement has been validated only for adult patients.

Prescription Use (Part 21 CFR 801 Subpart D)	___Yes__	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	__No___

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113657

Indications for Use X2

510(k) Number (if known):_____

Device Name: Philips X2 IntelliVue patient monitor, software revision J.03.

X2 Multi-Measurement Module:

The monitor is indicated for use by healthcare professionals whenever there is a need for monitoring the physiological parameters of patients.
The monitor is intended to be used for monitoring and recording of, and to generate alarms, for, multiple physiological parameters of adults, pediatrics, and neonates. The monitor is intended for use by trained healthcare professionals in a hospital environment.
The monitor is also intended for use during patient transport inside and outside of the hospital environment.
The monitor is only for use on one patient at a time. It is not intended for home use. Not a therapeutic device. The monitor is for prescription use only.
The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC 11).
ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.

Prescription Use (Part 21 CFR 801 Subpart D)	___Yes__	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	__No___

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510(k) Number K113657